

**Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention**

National Laboratory Certification Program (NLCP)

Program Document #41

Date: October 8, 2002

Subject: Revised Maintenance Inspection Fee for a Category V Laboratory

This notice establishes a revised maintenance inspection fee for a Category V laboratory participating in the NLCP.

For the past year, each certified laboratory has been submitting a non-negative specimen list that includes all drug positive specimens, adulterated specimens, substituted specimens, and split specimens reported for a 6-month period prior to an inspection to the NLCP contractor. The NLCP contractor reviews the list and directs the laboratory to make available all the batch data and documentation for a selected number of those non-negative specimen test results to facilitate review by the data auditors.

Our ongoing review of the amount of data the data auditors are capable of reviewing, clearly indicates that the percentage of non-negative specimen test results reviewed for Category V laboratories is significantly less than the percentage reviewed for the other inspection categories.

To be consistent in our quality assurance oversight, regardless of the size of the laboratory, we believe the percentage of non-negative specimen results reviewed by the data auditors for Category V laboratories must be increased. This increase would ensure that a sufficient percentage of non-negative test results will be reviewed to more consistently identify errors made by any laboratory.

Therefore, we are increasing the number of data auditors used for a Category V inspection from 4 to 6. The use of 6 data auditors increases the maintenance inspection fee for a Category V laboratory from \$29,000 to \$40,000.

This revised maintenance inspection fee for a Category V laboratory is effective immediately and will be evaluated periodically to ensure that a sufficient percentage of non-negative specimens are reviewed as the workload of the laboratory changes.

If you have any questions about the changes, please contact my staff at (301) 443-6014 or by email: wvogl@samhsa.gov

/Signed/

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